

The opinion in support of the decision being entered today was not written
for publication and is not binding precedent of the Board.

Paper No. 12

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ROBIN R. MILES,
PHILLIP BELGRADER, and CHRISTOPHER K. FULLER

Appeal No. 2003-1105
Application No. 09/738,461

ON BRIEF

Before ADAMS, MILLS and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

Having reviewed the record in this appeal, we have determined that this record is not in condition for decision on appeal. Accordingly we remand the application to the examiner to consider the following issues and to take appropriate action. Claims 1-9 are pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A method for detecting the end-point for PCR DNA amplification comprising:

providing at least a pair of electrodes in a fluidic channel. [sic]

producing an electric field across the electrodes,

directing a fluid containing single stranded DNA segments through the fluidic channel,

directing at least one ionically labeled probe through the fluidic channel for attachment to a complementary DNA segment causing the release of a labeled ion,

trapping the labeled ion in the electric field causing a conductivity change in the fluid between the electrodes,

measuring the change in conductivity as a change in the impedance between the pair of electrodes, and

using the impedance measurement to detect the presence of the trapped labeled ion for detecting the end-point for PCR DNA amplification.

No prior art is relied upon by the examiner.

GROUND OF REJECTION¹

- I. Claims 1-9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because the claimed method does not recite amplification steps.
- II. Claims 1-6 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite with regard to the “ionically labeled probe.”

¹ Claims 7-9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in the recitation of the phrase “[t]he improvement of [c]laim...” as it appears in the preamble of each claim. We note appellants’ statement (Brief, page 8) that they are “willing to amend [c]laims 7-9 to read -- [t]he improvement of the method of [c]laim 6.” This language appears to correspond to the examiner’s suggested claim language. See Answer, page 7. Accordingly, we encourage the examiner and appellants to work together to resolve this issue.

- III. Claims 1-9 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification that fails to adequately describe the claimed invention.

For the reasons that follow, we vacate² rejections I-III, and remand the administrative file to the examiner for further consideration.

DISCUSSION

I. The issues regarding the “ionically labeled probe”:

According to the examiner (Answer, page 4), “it is unclear in the second ‘directing’ step of claim 1 how ‘attachment to’ ... a complementary DNA segment would cause release of a labeled ion – one of ordinary skill in the art would expect no such release from mere hybridization of the ionically labeled probe to its target.” As we understand the Answer, the examiner has the same concern with regard to claim 6, which is written in Jepson format. Id.

In our opinion, however, the examiner’s concern goes to whether appellants’ specification provides an enabling description of the claimed invention under 35 U.S.C. § 112, first paragraph, not whether the claims are indefinite under 35 U.S.C. § 112, second paragraph. As our appellate reviewing court explains in Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991), the second paragraph of 35

² Lest there be any misunderstanding, the term “vacate” in this context means to set aside or to void. When the Board vacates an examiner’s rejection, the rejection is set aside and no longer exists. Therefore the issues set forth herein cannot be satisfied by a Supplemental Examiner’s Answer. See Ex parte Zambrano, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Int. 2000).

U.S.C. § 112 requires only that:

“[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” A decision as to whether a claim is invalid under this provision requires a determination whether those skilled in the art would understand what is claimed. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985).

Here the examiner appears to understand what is claimed in the “second ‘directing’ step” -- a labeled probe attaches to a complementary DNA segment causing the release of a labeled ion. Thus, the examiner’s concern does not appear to be whether the claimed invention is indefinite in the context of 35 U.S.C. § 112, second paragraph. Instead, it appears to be whether the specification provides an enabling description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. Stated differently, does the specification provide an enabling description of ionically labeled probes that would release a labeled ion when attached to a complementary DNA segment according to the claimed invention?

Since, in our opinion, the rejection is not based upon the correct legal standards, we vacate the rejection of claims 1-6 under 35 U.S.C. § 112, second paragraph, as indefinite with regard to the issue of the ionically labeled probe. This, however, does not end our discussion regarding the “ionically labeled probe.”

According to the examiner (Answer page 5), “the specification does not describe a single example of an ‘ionically labeled probe’, nor how digestion of such a probe by a polymerase ... will result in release of ionic label such that

change in conductivity can be measured.” In addition, the examiner finds (id.), “the specification is silent on how ... digested probe with the ionic label may be distinguished electronically from undigested probe bearing the label, or how this is to be accomplished via release of the label from the probe.” Accordingly, the examiner rejected claims 1-9 under the written description provision of 35 U.S.C. § 112, first paragraph, “as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) ... had possession of the claimed invention.”

In our opinion, however, the reasoning underlying this rejection is not that of a written description rejection but instead would appear to be more appropriate for a rejection based on the enablement provision of 35 U.S.C. § 112, first paragraph. The test for compliance with written description provision of 35 U.S.C. § 112, first paragraph has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (CAFC 1991). As appellants explain (Brief, page 9), ionic probes are known and while appellants are “not required to describe in detail that which is known,” their “specification does describe an ‘ionically labeled probe’, as set forth on page 5, beginning at line 11 and illustrated in Figure 1.” As set forth in Union Oil Co. of Cal. v. Atlantic Richfield Co., 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000), citation omitted, “[t]he written description requirement does not require the applicant ‘to describe exactly the

subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

Nevertheless, in maintaining the rejection under the written description provision of 35 U.S.C. § 112, first paragraph, the examiner finds (Answer, page 7), “one of ordinary skill in the art cannot carry out the disclosed invention without a description of how the ‘ionic probe’ is labeled in such a way that digested probe with the ionic label may be distinguished electronically from undigested probe bearing the label.” Again, it is our opinion that the reasoning behind the examiner’s rejection is consistent with the reasoning used to address the enablement provision of 35 U.S.C. § 112, first paragraph, rather than the written description provision of 35 U.S.C. § 112, first paragraph. Accordingly, it is our opinion that the rejection under 35 U.S.C. § 112, first paragraph, is not based on upon the correct legal standards. Accordingly we vacate the rejection under 35 U.S.C. § 112, first paragraph.

This brings us to the next question

II. Are claims 1-9 indefinite in not reciting amplification steps?

According to the examiner (Answer, page 4), “[c]laims 1-5 are confusing because while the preamble states the method ‘is for detecting the end point for PCR DNA amplification’, ... nothing in the claim body relates to amplification.” As we understand the Answer, the examiner has the same concern regarding claims 6-9 which are written in Jepson format. Id.

This rejection appears to be related to the examiner’s concern regarding the release of labeled ion upon attachment of the ionically labeled probe to a

complementary DNA. See supra. In this regard, we note the examiner's response to appellants' arguments (Answer, page 6), "page 5, lines 11-16 of the specification ... support the rejection; that is, it is recited that '...the polymerase enzyme will release a labeled ion 18...', and the whole point of the rejection is that there is no limitation regarding any polymerase enzyme in claim 1."

Curiously, however, the examiner included claim 4 in this rejection. Claim 4 further limits the method of claim 1 by requiring that "the labeled ion is release by polymerase enzyme reaction." We remind the examiner that a claim is not necessarily indefinite simply because its scope is broad. Accordingly, we vacate the rejection of claims 1-9 under 35 U.S.C. § 112, second paragraph, as it relates to the issue of the lack of amplification steps.

Having vacated the rejections under 35 U.S.C. § 112, first and second paragraphs, we are compelled to remand the application to the examiner. Upon receipt of the administrative file, we encourage the examiner to take a step back and construe the claimed invention as a person of ordinary skill in the art, using appellants' specification as a guide. After, having the opportunity to properly construe the claimed invention the examiner will be in a better position to determine whether appellants' specification enables the full scope of appellants' claimed invention.

If, after review of the administrative record, together with the relevant prior art, the examiner believes that a rejection should be made, we encourage the examiner to clearly articulate the statutory basis for any such rejection and to provide a fact-based reasoned analysis supporting the basis of the rejection.

FURTHER PROCEEDINGS

We are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

VACATED-IN-PART; REMANDED

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| Donald E. Adams |) | |
| Administrative Patent Judge |) | |
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| |) | BOARD OF PATENT |
| Demetra J. Mills |) | |
| Administrative Patent Judge |) | APPEALS AND |
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